K111183

MAY 24 2011

510(k) SUMMARY

Orthofix Ascent POCT System

Submitter Information

Name:	Orthofix Inc.
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Contact Person:	Darla Chew Director of Regulatory Affairs
Date Prepared:	April 26, 2011

Name of Device

Trade Name / Proprietary	Ascent® Posterior Occipital Cervical Thoracic (POCT) System
Name:	
Common Name:	Spinal Fixation System
Product Code:	KWP – Spinal Interlaminal Fixation Orthosis
Regulatory Classification:	Class II – 888.3050 – Spinal Interlaminal Fixation Orthosis
Review Panel:	Orthopedic Device Panel
Predicate Devices:	Blackstone Posterior Cervical System, K030197, SE 6-12-03 Ascent POCT System, K080394, SE 3-13-08 (Plate and Rod Modifications) Firebird Spinal Fixation System, Cobalt Chrome Rods, K092624, SE 9-25-2009

Reason for 510(k) Submission: New product offering

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Device Description

The Ascent® POCT System is a temporary, multiple component system comprised of a variety of non-sterile, single use components made of Titanium and Cobalt Chrome alloy that allow the surgeon to build a spinal implant construct. The system design is intended to promote immobilization and stabilization of spinal segments as an adjunct to fusion of the cervical and /or upper thoracic spine. Ascent POCT System consists of an assortment of rods, setscrews, cross connectors, axial connectors, lateral offset adapters, multi-axial screws, hooks, plates, bone screws, and Songer Cables. Ascent POCT system can also be linked to Orthofix Spinal Fixation System (SFS) using the Ascent Axial or Parallel Rod Connector or Transition Rods.

Intended Use / Indications for Use

When intended to promote fusion of the cervical spine and occipito-cervico-thoracic junction (Occiput-T3), the Ascent POCT System is indicated for:

a) degenerative disc disease (defined as neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies);
b) spondylolisthesis;
c) fracture/dislocation;
d) spinal stenosis;
e) atlanto-axial fracture with instability;
f) occipito-cervical dislocation;
g) tumors;
h) revision of previous cervical spine surgery

The occipital bone screws are limited to occipital fixation only. The use of the multi-axial screws is limited to placement in the upper thoracic spine (T1-T3) for the treatment of thoracic conditions only. They are not intended to be placed in the cervical spine. The lateral offset adapter is indicated for use in the upper thoracic spine (T1-T3). The hooks are intended to be placed from C1 to T3. The Songer Cable (titanium) System to be used with the Ascent Posterior Occipital Cervical Thoracic System allows for wire/cable attachment to the posterior cervical spine.

The Ascent Posterior Occipital Cervical Thoracic System can also be linked to the Orthofix Spinal Fixation System using the Ascent Axial or Parallel Rod Connector.

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Summary of the Technological Characteristics of the Device Compared to the Predicate Device

Characteristic	Orthofix Ascent Rods	Ascent POCT System (K030197 & K080394)	Firebird Spinal Fixation System, Cobalt Chrome Rods (K092624)
Function / Design	This system allows a surgeon to build a spinal implant construct.	This system allows a surgeon to build a spinal implant construct.	This system allows a surgeon to build a spinal implant construct.
Rod Configuration	Straight & Occipital	Straight & Occipital	Straight
Rod Sizes	Straight: 3.0 mm x 70, 120, 200 mm long; Occipital Rod	Straight: 3.0 mm x 70, 120, 200 mm long; Occipital Rod	Not relevant
Material	1) Cobalt Chrome Alloy, ASTM F1537 2) Titanium Alloy ASTM F136	Titanium Alloy ASTM F136	Cobalt Chrome Alloy, ASTM F1537

PERFORMANCE DATA – Summary of Non-Clinical Test Conducted for Determination of Substantial Equivalence

Characteristic	Standard / Test/ FDA Guidance
Static Compression Bending Test	ASTM F2706-08
Static Torsion Test	ASTM F2706-08
Dynamic Compression Bending Test	ASTM F2706-08
Dynamic Torsion Test	ASTM F2706-08

Performance Data Summary

Mechanical testing of the Orthofix Ascent POCT System was conducted in accordance to ASTM F2706-08 standard for Static & Dynamic Compression Bending test and ASTM F2706-08 standards for Static & Dynamic Torsion test. Test results demonstrated that the new, proposed Ascent rods are substantially equivalent to predicate devices that have the same intended use, similar indications, technological characteristics and principles of operation.

Substantial Equivalence

The Orthofix proposed Ascent rods are substantially equivalent in design, function, and intended use to the Orthofix Ascent POCT system rods. The original Ascent POCT System received 510(k) clearance under K030197 on June 12, 2003 with subsequent changes to the Ascent Occipital rod under K080394 SE March 13, 2008.

The Orthofix proposed Ascent rods are substantially equivalent in material composition to Firebird Spinal Fixation System, Cobalt Chrome Rods 510(k) K092624 (SE 9-25-2009).

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The difference between the modified rods and the predicate devices consist of minor dimensional changes for the Ascent Occipital rod, and the addition of Cobalt Chrome rods. Based on test results, these changes do not present any new / additional issues of safety or effectiveness therefore; the Orthofix proposed Ascent rods (part of the Ascent POCT System) are substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Orthofix, Inc.
% Ms. Darla Chew
Director of Regulatory Affairs
3451 Plano Parkway
Lewisville, TX 75056

MAY 24 2011

Re: K111183
Trade/Device Name: Ascent Posterior Occipital Cervical Thoracic System (Titanium & Cobalt Chrome Rods)
Regulation Number: 21 CFR 888.3050
Regulation Name: Spinal interlaminal fixation orthosis
Regulatory Class: Class II
Product Code: KWP
Dated: April 26, 2011
Received: April 27, 2011

Dear Ms. Chew:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Eric S. Keith

for Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATION FOR USE STATEMENT

510(k) Number (if known): K111183

Device Name: Ascent® Posterior Occipital Cervical Thoracic (POCT) System (Titanium & Cobalt Chrome Rods)

Indications for Use:

When intended to promote fusion of the cervical spine and occipito-cervico-thoracic junction (Occiput-T3), the Ascent POCT System is indicated for:

a. degenerative disc disease (defined as neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies);
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g. tumors;
h. revision of previous cervical spine surgery

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The Ascent Posterior Occipital Cervical Thoracic System can also be linked to the Orthofix Spinal Fixation System using the Ascent Axial or Parallel Rod Connector.

Prescription Use: X (Part 21 CFR 801 Subpart D) And / Or Over-The-Counter_____ (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices